Testimony of Caroline Smith DeWaal
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before the
Subcommittee on Domestic Policy of the
House Committee on Oversight and Government Reform

Washington, DC
July 29, 2009

Good morning Mr. Chairman, Ranking Member Jordan and Members of the Subcommittee. My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. We are supported principally by the 950,000 subscribers to our Nutrition Action HealthLetter and by foundation grants. We accept no government or industry funding.

Thank you for asking me here today to discuss the use of food safety marketing orders. CSPI has concerns about the increasing use of marketing orders as a vehicle for regulating safety. First, and foremost, it represents a further fracturing of our already dysfunctional food safety system. Fifteen different agencies administer 30 different laws that regulate food safety in this country.¹

Food Safety in Leafy Greens

Food-borne illness outbreaks related to fresh produce are a major public health problem. According to CSPI’s database of more than 5,000 food-borne illness outbreaks, fruits and vegetables caused 13 percent (768) of outbreaks with an identified food and pathogen and nearly 21 percent (35,060) of the associated illnesses between 1990 and 2006. Norovirus, Salmonella and E. coli O157:H7 illnesses have been traced to a wide variety of produce, including lettuce, salads, melons, sprouts, tomatoes, and many fruit- and vegetable-containing dishes.² Leafy greens and salads are among the top food categories, along with beef, chicken and seafood, that cause food-borne outbreaks and illnesses. In addition, the average size of produce outbreaks is larger than outbreaks from other foods, thus affecting more people.

² Center for Science in the Public Interest, Outbreak Alert! 2008, (Dec. 2008). This database of foodborne illness outbreaks is maintained by CSPI. It contains 17 years of data, from 1990–2006. Outbreaks are classified by both food vehicle and disease-causing agent. Food is classified by which agency regulates the product. During the years 1990 – 2006, there were 3,842 foodborne illness outbreaks from FDA-regulated foods (e.g. seafood, produce, eggs, milk); USDA regulated-foods (e.g. beef, poultry, pork) caused 1,567 outbreaks.
A series of produce outbreaks in the fall of 2006 was a wake up call for the public about the critical state of produce safety. Beginning in August, a nationwide outbreak of *E. coli* O157:H7 from bagged ready-to-eat spinach sickened 205 and killed at least three. Then in late September, *Salmonella* found in tomatoes sickened 183 restaurant patrons in 21 states throughout the nation. *E. coli* O157:H7 appeared in produce once more before the year’s end when two separate incidents of contaminated shredded iceberg lettuce sickened a total of 152 individuals at chain restaurants Taco Bell and Taco John.

While many produce outbreaks occurred prior to 2006, the spinach outbreak finally sourced the cause all the way to the farm. The Food and Drug Administration (FDA) traced the exact strain of the *E. coli* bacteria to a California spinach farm, finding it in nearby manure piles, in a creek and even in a wild pig. These findings definitively proved that the *E. coli* contamination that sickened so many people started on the farm.

While the produce outbreaks of fall 2006 have triggered a wake-up call for produce safety, large-scale produce outbreaks are not a new phenomenon in this country. Outbreaks from produce, both imported and domestic, have resulted in deaths, illnesses, both mild and severe, and great market disruptions.

Domestic produce is largely unregulated, and FDA has done little more than coax, urge, and warn producers to improve produce safety.

- In February 2004, following 14 outbreaks linked to lettuce and tomatoes, FDA sent a letter to firms that grow, pack, or ship fresh lettuce and/or fresh tomatoes asking them to review their current operations in light of the agency’s guidance.

- After seeing 18 outbreaks in 10 years involving *E. coli* O157:H7 in lettuce, FDA sent another letter in November 2005 specifically to California lettuce firms outlining actions the industry should take in order to ensure lettuce safety.

There is also some evidence that understanding of food safety problems on the farm is minimal. A qualitative study examining food safety practices used by Iowa produce growers was conducted by researchers from Iowa State University. Observational and in-depth interview techniques were used to assess current food safety practices at each operation. Researchers found that producers were conscious of product safety, but levels of awareness about risk varied. Areas that needed improvement included improved hand washing facilities and practices;

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provision of employee training; and the development of cleaning and sanitizing protocols for both products and food contact surfaces.\(^7\)

The importance of robust and reliable food safety practices on the farm cannot be understated. Leafy greens, once contaminated, can support, grow, and spread pathogens until consumed and while chlorination and other post-harvest controls can help reduce cross contamination between lots, they don’t make contaminated products truly safe to consume.

For example, a 2008 study examined the extent to which iceberg lettuce could be contaminated with *E. coli* O157:H7 by the field coring devices used during harvest.\(^8\) The study concluded that cells containing *E. coli* on the outer core of lettuce can be transferred to cut tissue during harvest. In addition, processing treatments using water and chlorine reduced but did not eliminate the pathogen. Once the contaminated cells infiltrate the cut tissue, they are protected from contact with chlorine.

On-going studies by the University of Georgia and Michigan State University, among others, are examining the ability of pathogens like *E. coli* to adhere to plant surfaces in the fields and to attach during washing and drying of leafy greens. For example, at the International Association of Food Protection conference this month, presenters showed using Germ Glo how bacteria can inhabit the washing systems used by the bagged lettuce industry today, with sporadic transfer of bacteria from one contaminated lot out to 300 pounds of lettuce.\(^9\)

Notably, although FDA has recently approved irradiation treatments for leafy greens consumers have not indicated a desire for irradiated produce. In fact, the growth of the organic food industry suggests that consumers are seeking less processed varieties of fruits and vegetables.\(^10\) The availability of many safe and wholesome organic fruits and vegetables demonstrates that safety need not be compromised, if robust safety practices are followed from the farm to the fork.

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\(^10\) Organic food sales are anticipated to increase an average of 18 percent each year from 2007 to 2010. A Harris Interactive® online survey conducted for Whole Foods Market during August 2008 showed that despite rising food prices, 79 percent of consumers do not want to compromise on food quality and 70 percent continue to buy the same amount of natural and organic foods as always. Primary reasons given for buying organic products by participants in The Hartman Group survey, *Organic2006: Consumer Attitudes & Behavior, Five Years Later & Into the Future*: “To avoid products that rely on pesticides or other chemicals”, “To avoid products that rely on antibiotics or growth hormones”, “For nutritional needs”, “To support the environment”, “To avoid genetically modified products”, “Health reasons other than allergies”, “They taste better”, and “To support sustainable agriculture”. Last accessed July 22, 2009 at http://www.ota.com/organic/mt/business.html.
Nature Abhors a Vacuum: Industry Use of AMS Marketing Programs for FDA-regulated Commodities

While FDA has jurisdiction over on-farm food safety, it has proven to be an ineffective regulator. The agency has often chosen to issue guidance instead of regulation. Guidance for industry are useful documents, but they do not give the food industries clear direction as to what practices are unacceptable.\(^{11}\) In addition, standards developed in the form of guidance are unenforceable when it comes to imported produce.

The old adage that nature abhors a vacuum is quite applicable in the business arena as well. With the rise in high-profile outbreaks, retailers are compelled to implement strict standards for produce items to both protect their customers from harm and their companies from liability. The absence of definitive rules leaves a significant hole in the fabric of food safety, allowing—even encouraging—the industry to weave standards of its own design.

One of the reasons for the proliferation of industry-defined food safety standards is that FDA has been hesitant to exercise its authority over on-farm safety. This authority is based in the FDA’s authority to ensure food products are not adulterated under section 402 of the Food, Drug, and Cosmetic Act, and in its authority to prevent the spread of communicable diseases delegated to the agency by section 361 of the Public Health Services Act. Citing these authorities, CSPI petitioned FDA to issue safety standards for on-farm food production in 2006 and again in 2008. Those petitions have been met with silence. Meanwhile, the industry has filled the gap through the ad hoc programs applicable to single commodities that are the target of today’s hearing.

With the concerns about produce outbreaks growing in recent years—and consumer confidence battered by repeated nationwide food recalls—it is not surprising that growers and handlers of fresh produce have cast around for a safety arbiter who can protect their interests as well as restore public confidence.

Whenever food safety problems emerge in a specific commodity, it is not unusual to see that industry look to the Agricultural Marketing Service at the United States Department of Agriculture (USDA) as a friendly regulator-of-choice. AMS is charged with “facilitat[ing] the competitive and efficient marketing of agricultural products.”\(^{12}\) It does so by overseeing “commodity programs.”\(^{13}\) These programs provide standardization, grading, and market news services for regulated commodities. AMS enforces the Perishable Agricultural Commodities Act and the Federal Seed Act. AMS commodity programs oversee marketing agreements and orders,\(^{14}\)

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\(^{11}\) This pattern of issuing guidance at FDA has continued, even after the change in administration. Just this year, for example, the agency has issued guidance rather than rules on peanut production to prevent *Salmonella* in the wake of the largest FDA recall in history.


\(^{13}\) AMS oversees five commodity programs: cotton, dairy, fruit and vegetable, livestock and seed, poultry and tobacco. USDA, *Commodity Areas*, at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&navID=CommodityAreas&leftNav=CommodityAreas&page=CommodityAreas&acct=AMSPW.
administer research and promotion programs, and purchase commodities for federal food programs.

Notably, AMS is not charged or equipped to monitor the safety of food; the primary focus of the AMS mandate is promotion. David Shipman, Acting Administrator of AMS stated this in his testimony before the House Committee on Agriculture in May, saying: “The mission of AMS is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace. AMS is not a food safety agency.”

Under the Agricultural Marketing Agreement Act (AMAA), AMS has two regulatory mechanisms that can be used to develop guidelines for the food industry: marketing agreements and marketing orders. Marketing orders are binding on all “handlers” (i.e., “processors, producers, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof”) of the regulated commodity in the geographic area covered by the order, while marketing agreements are binding only on those handlers who are voluntary signatories of the agreement. Marketing orders are necessarily limited to U.S. companies and have no effect on imports.

Currently, AMS oversees orders for 22 produce commodities. One of these, the almond industry, offers an example of AMS acting as a food safety regulator. Established in 1950, the Almond Board of California administers Marketing Order 981, to “promote the best quality almonds.” The Board describes the marketing order it oversees as having “quasi-governmental status,” and says that these orders are “used by many commodity groups as a means of combining their financial resources in pursuit of common interests of the industry.” As California’s largest tree crop, almonds enjoy a robust market in the U.S. and in the European Union, which accounts for over 50 percent of almond exports. However, the almond industry and its consumers have long grappled with two major safety concerns: Salmonella and aflatoxin.

Since 2001, the almond industry has experienced two significant outbreaks linked to Salmonella. While not common in almonds, the outbreaks sufficiently alarmed the industry to lead the Almond Board in 2006 to approve an Action Plan for food safety—the primary tenet of which was the pasteurization of all raw almonds to drastically limit rates of Salmonella.

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16 Id.
17 These are: almonds, apricots, avocados, cherries [sweet and tart], citrus [Florida and Texas], cranberries, dates, grapes, hazelnuts, kiwifruit, nectarines, olives, onions [Idaho-E. Oregon, S. Texas, Vidalia, and Walla Walla], peaches, pears [Oregon-Washington], pistachios, plums/Prunes [California and Washington], potatoes [Idaho-E. Oregon, Washington, Oregon-California, Colorado, and Virginia-North Carolina], raisins, spearmint oil, tomatoes, and walnuts. AMS, Industry Marketing and Promotion, Marketing Order Commodity Index, at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=LinktoCurr entFruitandVegetableMarketingOrders&rightNav1=LinktoCurrentFruitandVegetableMarketingOrders&topNav=&leftNav=&page=FVMarketingOrderIndex&resultType=&acct=fvmktord.
19 Almond Board of California, About the Almond Board, at http://www.almond-board.com/About/content.cfm?ItemNumber=544&snItemNumber=467.
20 Id.
Proposed to AMS as an amendment to Marketing Order 981, the rule was finalized in September of 2007.\(^{21}\)

The marketing order has also been used to manage other safety concerns. Almonds may also be contaminated with aflatoxins, naturally occurring chemicals produced by certain molds that may be carcinogenic.\(^{22}\) The European Union has one of the lowest allowable limits for aflatoxins—significantly lower than those allowed under AMS Marketing Order 981.\(^{23}\) In 2007, after repeatedly rejecting shipments offered for import, the EU concluded that the aflatoxin control system for California almonds was inadequate, and moved to require testing of 100 percent of shipments into the EU. In response, the Almond Board created a voluntary protocol, the Voluntary Alfatoxin Sampling Plan (VASP), to test almonds prior to export. Under that plan, growers could offer 100 percent of their product for sampling prior to shipment; in exchange, the EU agreed to test only 5 percent of imported shipments that have been through VASP.\(^{24}\)

Another industry overseen by AMS is the shell egg industry.\(^{25}\) Under current law, that industry is covered by a confusing array of laws, regulations, and voluntary programs administered by three federal agencies:

- USDA’s Animal and Plant Health Inspection Service (APHIS) is responsible for preventing the spread of animal disease, and oversees the health of chickens used in egg production;
- FDA is the agency charged with ensuring shell egg safety, just this month announced its rule to minimize *Salmonella enteriditis* (SE) in eggs, nearly two decades after the problem emerged; and
- AMS provides voluntary shell egg grading services and conducts inspection of all shell egg plants four times a year for cleanliness and quality control.

With its current budget and staffing, FDA conducts safety inspections in shell egg facilities approximately once every 10 years. Ironically, while AMS inspects egg plants quarterly, it does not check for SE contamination.

For years, the AMS egg grading program has been the primary arbiter of egg quality in the U.S. The voluntary grading program for shell eggs is paid for by participating producers, and approximately 40 percent of the nation’s shell egg producers participate. Participating egg-packing plants are inspected for sanitation and proper washing of eggs, but not to determine


\(^{23}\) 7 C.F.R. § 981.

\(^{24}\) Almond Board of California, *supra* note 22.

\(^{25}\) Shell eggs refer to eggs within their shells, which are regulated by the agencies listed here. Egg products (pasteurized liquid or powder eggs) are inspected by USDA’s Food Safety and Inspection Service (FSIS) under the Meat and Poultry Act’s continuous inspection provision.

whether the eggs are free of microbial contaminants.

AMS is also responsible for the Shell Egg Surveillance Program. AMS inspectors visit shell egg plants four times a year to ensure that dirty eggs, cracked eggs, and eggs with blood spots are properly disposed of and are not sold to consumers in cartons. However, this program does not include testing eggs for SE and diversion of infected eggs to pasteurization plants.

Notably, these programs may instill a false sense of security for both the industry and consumers. The quality AMS inspects for has little relationship to the safety consumers deserve. For many years, for example, there were conflicting temperature requirements for the transport of raw shell eggs: AMS mandated 60˚F, the temperature at which quality is maintained, while another USDA agency with oversight over pasteurized eggs mandated 45˚F, the temperature at which bacterial growth is restricted.

**Voluntary Standards Should Not Replace Government Action and Oversight**

In 2007, in the aftermath of a devastating *E. coli* O157:H7 outbreak in spinach, California growers formed the California Leafy Greens Products Handler Marketing Agreement, a voluntary, membership-based organization. The group created its own commodity-specific GAP guide (the *Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens*, hereinafter “CALGMA”) to respond to a clear need for greater safety controls on their products. Nearly 120 handlers, representing approximately 99 percent of the volume of California leafy greens, have joined the CALGMA. These companies have voluntarily committed to sell products grown in compliance with the food safety practices accepted by the LGMA board.

While accepted by both the California leafy green industry and the state Department of Agriculture, this voluntary guidance and marketing agreement has not proven effective, as indicated by several recent outbreaks:

- In May 2008, bagged Romaine lettuce sickened 10 people in Washington state with *E. coli* O157:H7. The lettuce was traced to Salinas Valley, California.

- In September 2008, California-produced lettuce was implicated in an *E. coli* outbreak that sickened 40 people in five states. Michigan determined that the lettuce was grown in California and processed in Detroit.

The CALGMA food safety practice standards were developed by university and industry scientists, food safety experts and farmers, shippers and processors, and appear quite robust. They are much stronger than FDA’s existing guidelines, and other standards adopted internationally. The FDA—though responsible for the regulation of these products—was noticeably absent from the creation of the guidelines. The government’s role in the agreement is secondary: the California Department of Food and Agriculture (CDFA) employs specially certified inspectors to conduct CALGMA audits. These inspectors operate with oversight from CDFA, but are certified and trained by USDA under the auspices of the National Good Agricultural Practice program at AMS.
As a voluntary program, members can simply elect not to participate, and there is no penalty for doing so beyond the removal of a marketing seal on their packaging. While CALGMA has attempted to fill the void left by the lack of government action, such a program is not an appropriate long-term substitute for comprehensive, mandatory regulation to ensure the safety of the food supply.

In 2008, CSPI and the Produce Safety Project, an Initiative of the Pew Charitable Trusts at Georgetown University, undertook an independent analysis of the various guidelines and agreements currently in use for fresh produce, including the CALGMA, FDA’s 1998 Produce Guidance, Codex provisions on fresh produce, and several others. The comparison focused on major issue areas deemed by the researchers to be fundamental to food safety on the farm. The comparison also brought into stark relief the differences between and gaps in the various standards.

While the CALGMA performed well in the comparison, indicating that many areas of concern appear to be addressed in the document, this doesn’t change the fact that the CALGMA is a voluntary set of opinions and recommendations set forth by the industry for the industry. They do not carry the weight of the U.S. government.

Further, the patchwork nature of these standards create uncertainty for retailers, which can result in the rise in the use of private standards stipulating particular practices or measures for growers. Growers and environmentalists have questioned the use of private standards that require practices recently exposed as causing major disruption of growers and major environmental impacts in California.

The Food Safety Enhancement Act (H.R. 2749) currently before the House of Representatives addresses this issue head on, by requiring FDA to consider both food safety and environmental impacts when promulgating rules for food production. H.R. 2749 requires the standards to take account of small-scale and diversified farming, wildlife habitat, conservation practices, water-shed protection and organic production methods. This provides an appropriate focus on public safety, while protecting aspects of sustainable and organic farming that we all value. Further, the very process of rulemaking offers an opportunity for notice and comment among all stakeholders, with the aim of ensuring both the public health and the protection of the environment. Such notice and comment is of course absent from the boardrooms where today’s private contracts are drafted.


28 Areas of comparison included agricultural water (microbial standards, sampling, and assessment), growing fields (prior use, flooding), manure (prohibitions on raw manure, composting standards, sampling, storage and treatment), animal control (exclusion of animals, set distance from CAFOs), worker health and hygiene (personal service areas, toilets, destruction of contaminated product), and field sanitation (sanitizing harvesting equipment, disposition of damaged harvest containers). Produce Safety Project, Comparison of GAPs Governing The Growing and Harvesting of Fresh Produce, 2009 at http://www.producesafetyproject.org (the Produce Safety Project is an initiative of the Pew Charitable Trusts at Georgetown University.)
Over the past year, CSPI has been working closely with the Association of Food and Drug Officials (AFDO), industry representatives, and government regulators to draft food safety standards for the produce industry. These standards address issues relating to the production of all types of produce, including leafy greens, fruits, and other vegetables that are commonly eaten raw. The goal of the project is to produce a comprehensive statement of best practices across the produce industry, developed by all stakeholders—not only industry, but also consumer, academic, and government.

Once complete, it is hoped that the FDA will codify these guidelines into mandatory regulations with the authority and enforcement of the federal government behind them. Unlike the CALGMA, standards enacted by FDA would be adopted through a transparent, public process, including a notice and comment period that would allow environmental impacts to be fully discussed. When codified, the regulations would apply to all members of the industry—not simply those who choose to comply. And importantly, those standards would apply to imported produce as well as domestic, so that consumers could be assured of safe products whether they were produced in California or Mexico.

Marketing Orders Do Not Address Imported Food

Americans eat about 260 pounds of imported foods—approximately 13 percent of their total diet—each year. U.S. imports for 2006 reached a record value of $65.3 billion, roughly $6 billion higher than the year before. Overall, U.S. imports of agricultural and seafood products from all countries have increased by nearly 50 percent over the last decade, with certain countries and commodities showing exponentially greater increases.

Americans enjoy a variety of fresh fruits and vegetables year-round, and supplying this demand is done by importing produce from around the world. In fact, one-quarter of our fruit, both fresh and frozen, is imported. But lack of adequate import controls has lead to numerous large and occasionally deadly outbreaks linked to imported food. Last summer, an outbreak of *Salmonella Saintpaul* was linked first to tomatoes and then jalapeno peppers from Mexico. In the previous several years, Americans were sickened from green onions, cantaloupes, and strawberries from Mexico, and raspberries from Guatemala. These outbreaks have caused thousands of illnesses and several deaths, and have had a lasting effect on consumer confidence.

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29 Over 1,400 people in 43 states were sickened, with 286 hospitalized and two deaths. CDC, *Outbreak of Salmonella Serotype Saintpaul Infections Associated with Multiple Raw Produce Items --- United States, 2008*, MMWR Weekly 57(34):929-934, Aug. 29, 2008, at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5734a1.htm.

30 In 2003, a major Hepatitis A outbreak linked to raw green onions used in restaurant salsa sickened 555 people in Pennsylvania, killing three of them. Traceback by FDA indicated that green onions supplied to the restaurant were grown in Mexico under conditions where contamination with human waste was likely. Green onions from this area were also linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier that fall.

31 Three multistate outbreaks of *Salmonella* serotype Poona infections associated with cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000-2002. FDA conducted traceback investigations and determined that the cantaloupes were from farms in Mexico.

32 In 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries. The strawberries were harvested in Mexico and processed and frozen in southern California before they were distributed...
Unfortunately, the marketing orders and agreements overseen by AMS offer no additional protection to consumers from imported food. Thus, Spanish almonds are sold alongside California almonds in many retail outlets, but only one has been processed to minimize harmful *Salmonella* bacteria. This critical gap in protection is a severe shortcoming of the AMS commodity order.

The most important benefit of a mandatory regulatory program is that it would help assure that all growers and processors – domestic and foreign – implement good agricultural practices. While many of the best growers and processors use HACCP-like systems and adhere to good agricultural practices, compliance is far from universal.

**Conclusion**

Food-borne illness outbreaks related to fresh produce are a major public health problem. Risk prevention, detection and control measures must be in place at every step of fresh-cut produce production to help ensure food safety risks are minimized. Industry-operated marketing orders are not an effective or appropriate public health response to address the food safety problems cropping up in fruits and vegetables. Ultimately, strong regulatory requirements for fresh-cut produce—promulgated and enforced by the responsible regulatory authority—would provide appropriate protection for the public. Congress should act to curtail the trend toward use of marketing orders by providing FDA with the authority and resources it needs to carry out its food safety responsibilities.

Important new legislation, H.R. 2749, the Food Safety Enhancement Act, includes a provision that clarifies FDA’s food safety role on the farm. It will require FDA to establish science and risk-based standards to prevent contamination of farm produce. The bill, by remedying FDA’s refusal to act under its existing authority, is the best hope for ending the trend toward private industry-designed standards enforced by regulators of choice. The most important benefit of a mandatory regulatory program is that it would help assure that all growers and processors – domestic and foreign – implement good agricultural practices.

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33 In 1996 and 1997, thousands of people became ill in both the U.S. and Canada from a parasite, *Cyclospora*, on raspberries grown in Guatemala. Illness associated with *Cyclospora* includes watery diarrhea and persistent fatigue, which can persist for a month or longer if untreated. *Cyclospora* is chlorine-resistant and can be transmitted through water or from infected handlers.